NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ALLYN TURNOFSKY, individually and on behalf of others similarly situated, Plaintiff, v. ELECTROCORE, INC. *et al.*, Defendants.	Civ. No. 19-18400 **OPINION**

THOMPSON, U.S.D.J.

INTRODUCTION

This matter comes before the Court upon the Motion to Dismiss filed by Defendants electroCore, Inc. ("electroCore"), Francis R. Amato, Glenn S. Vraniak, Brian Posner, Carrie S. Cox, Michael G. Atieh, Joseph P. Errico, Nicholas Colucci, Thomas J. Errico, Trevor J. Moody, Michael W. Ross, David M. Rubin, James L.L. Tullis, Stephen L. Ondra, Core Ventures II, LLC ("CV II"), Core Ventures IV, LLC ("CV IV"), Evercore Group L.L.C. ("Evercore"), Cantor Fitzgerald & Co. ("Cantor Fitzgerald"), JMP Securities LLC ("JMP"), and BTIG, LLC ("BTIG") (collectively, "Defendants") (ECF No. 42), and the Motion to Strike Certain Documents Attached to and Referenced in Defendants' Motion to Dismiss filed by Lead Plaintiff Carole Tibbs ("Motion to Strike") (ECF No. 48). The Court has decided the Motions based on the written submissions of the parties and oral argument. For the reasons stated herein, Lead Plaintiff Carole Tibbs' Motion to Strike (ECF No. 48) is granted in part and denied in part, and Defendants' Motion to Dismiss (ECF No. 42) is granted.

BACKGROUND

I. Factual Background

electroCore is a bioelectronic medicine company. (Am. Compl. ¶ 48, ECF No. 31.) Its flagship product is called gammaCore. (*Id.* ¶ 50.) gammaCore stimulates the vagus nerve, the longest cranial nerve carrying signals from the digestive system to the brain, to treat cluster headaches and migraines. (*See id.* ¶¶ 50, 52–54.) The original gammaCore product dispensed therapy on a thirty-one-day prescription basis. (*Id.* ¶ 51.) Its successor, gammaCore Sapphire, is intended for multi-year use. (*Id.*)

In April 2017, the U.S. Food and Drug Administration ("FDA") cleared commercial sales of gammaCore for acute treatment of pain associated with cluster headaches in adults. (*Id.* ¶ 52.) The FDA granted clearance for gammaCore Sapphire in December 2017. (*Id.*) In January 2018, electroCore received FDA clearance to use gammaCore for acute treatment of pain associated with migraines in adults. (*Id.* ¶ 54.)

electroCore announced its Initial Public Offering ("IPO") in May 2018. (*Id.* ¶ 63.) electroCore filed its first Form S-1 Registration Statement with the U.S. Securities and Exchange Commission ("SEC") on May 21, 2018. (*Id.* ¶ 105.) electroCore filed amendments to the Registration Statement in June 2018, and the SEC declared the Registration Statement effective on June 21, 2018. (*Id.*) On June 25, 2018, electroCore filed a Prospectus with the SEC. (*Id.* ¶ 106.) electroCore issued and sold 5,980,000 shares of common stock, totaling proceeds of approximately $77.7 million. (*Id.* ¶ 107.)

In the Amended Complaint, Lead Plaintiff Carole Tibbs ("Plaintiff") alleges that Defendants—electroCore, officers and directors of electroCore, private equity investment firms, and underwriters of electroCore's IPO, (*see id.* ¶¶ 16–35)—made several material

misrepresentations and/or omissions in electroCore's Registration Statement, SEC filings, press releases, and conference calls. The alleged misrepresentations and/or omissions relate to competition, third-party payor coverage, physician acceptance, financial challenges, product challenges, personnel challenges, and clinical trial data. Plaintiff relies on statements of several confidential witnesses to support her claims. (*See, e.g.*, *id.* ¶¶ 66, 68, 70–92, 94–97, 203–05.)

II. Procedural History

The initial Complaint was filed on September 26, 2019. (ECF No. 1.) On April 24, 2020, the Court appointed Carole Tibbs as Lead Plaintiff. (Order at 2, ECF No. 19.)

On July 17, 2020, Plaintiff filed the operative Amended Complaint. (ECF No. 31.) The Amended Complaint alleges five counts:

- (1) violations of § 11 of the Securities Act of 1933, 15 U.S.C. § 77a *et seq.* (the "Securities Act"), against Defendants electroCore, Amato, Vraniak, J. Errico, T. Errico, Cox, Atieh, Colucci, Moody, Ondra, Ross, Rubin, Tullis, Evercore, Cantor Fitzgerald, JMP, and BTIG (collectively, the "Securities Act Defendants") (Am. Compl. ¶¶ 127–39);
- (2) violations of § 12(a)(2) of the Securities Act against Defendants electroCore, Evercore, Cantor Fitzgerald, JMP, and BTIG (Am. Compl. ¶¶ 140–48);
- (3) violations of § 15 of the Securities Act against Defendants Amato, Vraniak, J. Errico, T. Errico, Cox, Atieh, Colucci, Moody, Ondra, Ross, Rubin, Tullis, CV II, and CV IV (Am. Compl. ¶¶ 149–56);
- (4) violations of § 10(b) of the Securities Exchange Act of 1934, 15 U.S.C. § 78a *et seq.* (the "Exchange Act"), and SEC Rule 10b-5, 17 C.F.R. § 240.10b-5, against Defendants electroCore, Amato, Vraniak, Posner, J. Errico, T. Errico, Cox, Atieh, Colucci, Moody,

Ondra, and Tullis (collectively, the "Exchange Act Defendants") (Am. Compl. ¶¶ 221–32); and

- (5) violations of § 20(a) of the Exchange Act against Defendants Amato, Vraniak, Posner, J. Errico, T. Errico, Cox, Atieh, Colucci, Moody, Ondra, and Tullis (Am. Compl. ¶¶ 233–38).

Plaintiff brings her claims on behalf of a class of purchasers of electroCore stock. (*See id.* ¶ 42.)

On September 15, 2020, Defendants filed a Motion to Dismiss. (ECF No. 42.) Plaintiff filed an Opposition (ECF No. 47), and Defendants filed a Reply (ECF No. 51). Plaintiff filed a Motion to Strike. (ECF No. 48.) Defendants filed an Opposition (ECF No. 52), and Plaintiff filed a Reply (ECF No. 53). The Court held oral argument on June 18, 2021. The Motion to Dismiss and Motion to Strike are presently before the Court.

LEGAL STANDARD

"All securities fraud claims are subject to Rule 9(b) [of the Federal Rules of Civil Procedure], which requires [a] plaintiff to 'state with particularity the circumstances constituting fraud or mistake.'" *Williams v. Globus Med., Inc.*, 869 F.3d 235, 240 (3d Cir. 2017) (quoting Fed. R. Civ. P. 9(b)). "In addition, the [Private] Securities Litigation Reform Act [("PSLRA")] imposes two heightened pleading requirements above the normal Rule 12(b)(6) standard." *Id.* First, the complaint must "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1). "This standard requires plaintiffs to plead the who, what, when, where and how: the first paragraph of any newspaper story." *See Inst. Inv. Grp. v. Avaya, Inc.*, 564 F.3d 242, 253 (3d Cir. 2009) (internal quotation marks

omitted). Second, "the complaint shall, with respect to each act or omission alleged to violate this chapter, state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." § 78u-4(b)(2)(A). "Where a plaintiff's [Securities Act] claims are not grounded in allegations of fraud, the liberal notice pleading requirements of Rule 8 [of the Federal Rules of Civil Procedure] apply" to those claims. *In re Suprema Specialties, Inc. Sec. Litig.*, 438 F.3d 256, 270 (3d Cir. 2006).

DISCUSSION

I. Motion to Strike

Generally, a district court must confine its review to the pleadings on a Rule 12(b)(6) motion, *see* Fed. R. Civ. P. 12(d), but "a court may consider certain narrowly defined types of material" beyond the pleadings, *In re Rockefeller Ctr. Props., Inc. Sec. Litig.*, 184 F.3d 280, 287 (3d Cir. 1999). The court may consider "matters incorporated by reference or integral to the claim, items subject to judicial notice, matters of public record, orders, [and] items appearing in the record of the case." *Buck v. Hampton Twp. Sch. Dist.*, 452 F.3d 256, 260 (3d Cir. 2006). The court may also consider "document[s] . . . explicitly relied upon in the complaint . . . without converting the motion [to dismiss] into one for summary judgment." *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997) (emphasis omitted).

Plaintiff requests that the Court strike the following documents: (i) electroCore's 2019 Form 10-K (ECF No. 42-5); (ii) an excerpt from the FDA's website apparently reflecting the emergency-use authorization of gammaCore as a treatment for asthma exacerbations from the COVID-19 virus (ECF No. 42-6); and (iii) several press releases and news articles cited in Defendants' Motion to Dismiss. (*See* Mot. to Strike at 4–7, ECF No. 48-1.)

A. *2019 Form 10-K*

The Court strikes the 2019 Form 10-K attached to the Motion to Dismiss. Defendants submit this document to show that the FDA cleared gammaCore for migraine prevention in March 2020. (*See* Mot. to Dismiss at 6 n.5, ECF No. 42-1.) The 2019 Form 10-K is not referenced or relied upon in the Amended Complaint. The 2019 Form 10-K, signed in March 2020, also post-dates the class period and has minimal relevance to the issues presented in the Motion to Dismiss. (*See* 2019 Form 10-K at 115–19, ECF No. 42-5.)[1] Therefore, the Court will not consider the 2019 Form 10-K at this stage of the case. *See Hall v. Johnson & Johnson*, 2019 WL 7207491, at *10 (D.N.J. Dec. 27, 2019) (declining to take judicial notice of FDA website excerpts because they post-dated the class period and had "minimal relevance to the claims at issue"); *In re PTC Therapeutics, Inc. Sec. Litig.*, 2017 WL 3705801, at *3 n.5 (D.N.J. Aug. 28, 2017) (declining to take judicial notice of post-class-period SEC filings because their "relevance to the issues" was "quite low").

B. *FDA's Emergency-Use Authorization*

For similar reasons, the Court strikes the FDA's emergency-use authorization of gammaCore as a treatment for asthma exacerbations from COVID-19. The emergency-use authorization post-dates the class period. (*See* FDA Emergency-Use Authorization at 9, ECF No. 42-6.) The emergency-use authorization is also unrelated to the misstatements and omissions alleged by Plaintiff. Therefore, the Court will not consider it at this point. *See Hall*, 2019 WL 7207491, at *10; *PTC Therapeutics*, 2017 WL 3705801, at *3 n.5.

[1] The class period is from June 22, 2018 to September 25, 2019. (Am. Compl. at 1, ECF No. 31.)

C. *Press Releases and News Articles*

The Court, however, declines to strike Defendants' references to press releases and news articles in the Motion to Dismiss. Defendants rely on those documents to highlight publicly available information about gammaCore's competitors in 2017 and 2018. (*See* Mot. to Dismiss at 26–27, 30–31.) The Court agrees with Defendants' argument that the press releases and news articles are subject to judicial notice. (*See id.* at 26 n.16.) In securities actions, courts in the Third Circuit may take judicial notice of news articles at the motion-to-dismiss stage. *See Benak v. Alliance Cap. Mgmt. L.P.*, 435 F.3d 396, 401 n.15 (3d Cir. 2006). The articles, however, "serve only to indicate what was in the public realm at the time [they were published], not whether the contents of those articles were in fact true." *Id.* Therefore, Defendants' references to press releases and news articles are not stricken, but the Court will not consider the articles for the truth of their contents. Defendants' Motion to Strike is accordingly granted in part and denied in part.

II. Count 1: Section 11 of the Securities Act

Section 11 of the Securities Act creates a private cause of action in cases where a registration statement "contain[s] an untrue statement of a material fact or omit[s] to state a material fact required to be stated therein or necessary to make the statements therein not misleading." 15 U.S.C. § 77k. "Section 11 imposes near-strict liability for untruths and omissions made in a registration statement." *Obasi Inv. LTD v. Tibet Pharms., Inc.*, 931 F.3d 179, 182 (3d Cir. 2019). An omitted fact is material where "there is a substantial likelihood that a reasonable [investor] would consider it important." *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175, 196 (2015) (quoting *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 449 (1976)). There is no "affirmative duty to disclose any and all material

information. Disclosure is required only when necessary to make . . . statements made, in light of the circumstances under which they were made, not misleading." *See Williams*, 869 F.3d at 241 (internal quotation marks omitted) (Exchange Act case). "[W]hether a statement is 'misleading' depends on the perspective of a reasonable investor: The inquiry . . . is objective." *Omnicare*, 575 U.S. at 186–87.

A. *Pleading Standard for Securities Act Claims*

Rule 8 of the Federal Rules of Civil Procedure applies to Plaintiff's Securities Act claims. Where Securities Act claims allege ordinary negligence and are pled separately from Exchange Act claims, "[t]hat is enough to avoid triggering Rule 9(b)." *See Suprema*, 438 F.3d at 273. Plaintiff's Securities Act claims "expressly disclaim[] any allegations that could be construed as alleging fraud or intentional or reckless misconduct." (Am. Compl. ¶ 98.) Plaintiff alleges that the Securities Act Defendants acted with ordinary negligence. (*See id.* ¶ 108.) And Plaintiff explicitly separated her Exchange Act allegations from her Securities Act allegations. (*See id.* ¶ 157.) Therefore, the Court applies Rule 8, not Rule 9(b) or the PSLRA's heightened pleading standard, to Plaintiff's Securities Act claims.

B. *Alleged Misstatements and Omissions*

1. Competition

The Registration Statement described what electroCore believed to be its competitive strengths and "novel and propriet[ary] self-administered bioelectronics therapy." (*Id.* ¶ 109 (quoting Registration Statement at 2, Defs.' Ex. 1, ECF No. 42-3); *see also id.* ¶ 110 (listing electroCore's "competitive strengths," including "unlock[ing] the long-held potential of [vagus nerve stimulation ("VNS")]," "[c]ommercializ[ation] . . . through traditional pharmaceutical channels," "[h]ighly scalable and low investment manufacturing with digital refills," "[p]otential

for rapid label expansion in headache and regulatory approval in additional indications," and a "[h]ighly experienced management team" (quoting Registration Statement at 2).) The Registration Statement also explained that gammaCore's advantages include its "ease of use and suitability to be applied for as many attacks as a patient experiences per day, without the frequency-of-use restrictions and contraindications associated with other treatments." (*Id.* ¶ 111 (quoting Registration Statement at 4).)

Plaintiff argues that those statements reflected misstatements and/or omissions because "several other competitors were also being granted FDA clearance for the same uses and/or entering the market" while electroCore was obtaining FDA clearance (*id.* ¶ 56; *see also id.* ¶¶ 57–62 (describing competitors' developments)); a "new insurance-covered drug specifically used for migraine prevention" was "being introduced to the market" (*id.* ¶ 97); and "several other similar medical devices" were "already approved for both acute and preventative treatment and comparable [in effectiveness]" (*id.* ¶ 120(i) (emphasis omitted; internal quotation marks omitted)). Based on these alleged facts, Plaintiff submits that gammaCore "did not enjoy any competitive advantages over other treatments for [cluster headaches] and migraines." (*Id.*)

Plaintiff has not demonstrated that the Securities Act Defendants' statements about competition were plausibly false. Plaintiff does not allege sufficient information contradicting the Registration Statement's specific claims about gammaCore's advantages.

Nor has Plaintiff demonstrated that the Registration Statement omitted facts that plausibly made the statements about competition materially misleading. As an initial matter, some of the statements are opinions. The preamble to the Registration Statement's list of "competitive strengths" reads, "We *believe* the competitive strengths of our company and our novel and proprietary self-administered bioelectronic therapy include [the following] . . . ."

(Registration Statement at 2 (emphasis added).) The Registration Statement's disclosure on "Competition" provides, "While we *believe* that our proprietary gammaCore therapy provides us with competitive advantages, we face potential competition from many different sources . . . ." (*Id.* at 132 (emphasis added).)

Opinions can violate § 11 in certain circumstances. An opinion "is not misleading just because external facts show the opinion to be incorrect." *Omnicare*, 575 U.S. at 188. But an opinion can be actionable if the issuer does not honestly hold the opinion and the misrepresentation is material. *See id.* at 184–85. An opinion can also violate § 11 if statements of fact embedded in the opinion are untrue and the misrepresentation is material. *See id.* at 185–86. And an opinion can violate § 11 if an investor "identif[ies] particular (and material) facts going to the basis for the issuer's opinion—facts about the inquiry the issuer did or did not conduct or the knowledge it did or did not have—whose omission makes the opinion statement at issue misleading to a reasonable person reading the statement fairly and in context." *See id.* at 194. "That is no small task for an investor." *Id.*

Plaintiff does not allege that the Securities Act Defendants did not believe their opinions about gammaCore's competitive strengths. Plaintiff does not point to false statements embedded in the opinions. And Plaintiff does not identify particular facts about the Securities Act Defendants' bases for the opinions that plausibly make the opinions materially misleading.

Moreover, Plaintiff has not plausibly alleged that the statement about gammaCore's "ease of use and suitability to be applied for as many attacks as a patient experiences per day, without the frequency-of-use restrictions and contraindications associated with other treatments," was misleading. The statement does not imply that similar medical devices were not entering the market. The statement does not suggest that competitors had not been granted FDA clearance for

the same uses or that competitors had not been approved for acute and preventative treatment. Nor does the statement intimate that other medical devices were incomparable in effectiveness; it simply highlights one relative strength of gammaCore.

The Registration Statement's extensive competition-related disclosures further undermine Plaintiff's argument that omissions about competition made other statements misleading. Courts analyzing whether an opinion is misleading to a reasonable investor must "address the statement's context." *Id.* at 196. "That means the court must take account of whatever facts [the issuer] *did* provide[,] . . . as well as any other hedges, disclaimers, or qualifications it included in its registration statement." *Id.* The Registration Statement disclosed competitors' advantages[2] and competitors' developments.[3] Considering the extent and detail of the Registration

[2] (*See, e.g.*, Registration Statement at 16, Defs.' Ex. 1, ECF No. 42-3 (stating that electroCore "must successfully demonstrate to physicians the merits of [gammaCore] for the acute treatment of [cluster headaches] and . . . migraine, compared to our competitors' products, including products recently approved or being developed in Phase 3," and listing seven competitors by name); *id.* at 25 (warning that electroCore "may be unable to gain broader market acceptance . . . [or] commercialize [gammaCore]" because of "established competitors with strong relationships with customers, including physicians, hospitals and third-party suppliers"); *id.* at 26 (explaining that, "[i]f our competitors are better able to develop and market [cluster headache] and migraine treatments that are safer, more effective, less costly, easier to use or otherwise more attractive than [gammaCore], our business will be adversely impacted"; noting that electroCore "face[s] significant competition [that electroCore] believes will intensify over time"; and listing twelve advantages of electroCore's competitors); *id.* at 27 (disclosing that electroCore "face[s] a particular challenge overcoming the long-standing practices by some physicians of using the headache products of . . . larger, more established competitors"); *id.* (stating that gammaCore's competitors are or will be conducting clinical trials "to demonstrate the results of their headache products" and the results of the trials may be "equivalent to, or potentially better than, the results of [electroCore's] clinical trials"); *id.* at 132 (warning that "[m]any of the companies [electroCore] [is] competing with . . . have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs," and providing an overview of competing treatments for cluster headaches and migraines).)

[3] (*See, e.g.*, Registration Statement at 16 (referencing "products recently approved or being developed in Phase 3 by Allergan plc, Amgen Inc. (with a co-marketing arrangement with

Statement's disclosures on competition, the alleged omissions do not make the statements about gammaCore's competitive strengths misleading. Therefore, Plaintiff's competition-related allegations do not support her § 11 claim.

2. Third-Party Payor Coverage

The Registration Statement explained that electroCore had

> agreements in place with commercial payors that [electroCore] believe[d], based on [its] estimates, w[ould] provide for reimbursement for gammaCore as a pharmacy benefit for approximately 17 million commercial lives[,] with such number expected to increase to as many as 45 million lives under these agreements over the next several calendar quarters.

(Registration Statement at 2; *see also id.* at 4–6.) The Registration Statement added that electroCore's "access negotiations . . . entered the active clinical review stage with more than a dozen additional insurance plans covering approximately 120 million additional commercial lives." (*Id.* at 6, 130.)

Plaintiff has not plausibly pled that the Registration Statement's statements about payor coverage were false. In her Opposition, Plaintiff argues that electroCore had only *one* agreement in place, the CVS Caremark Agreement, at the time of electroCore's IPO. (*See* Opp'n at 4, ECF No. 47.) At oral argument, Plaintiff's counsel asserted that electroCore had *no* agreements in

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Novartis International AG), Biohaven Pharmac[e]uticals, Inc., Eli Lilly and Company, Alder Biopharmac[e]uticals, Inc. and Teva Pharmaceutical Industries Ltd., for use in treating patients with cluster and migraine headaches"); *id.* at 132 (referencing "[s]mall molecule [calcitonin gene-related peptide ("CGRP")] receptor agonists . . . currently in Phase 3 development by Allergan plc and Biohaven Pharmaceuticals Inc. for the acute treatment of migraines," "[c]ertain classes of anti-epileptic medicine and beta-blocker medications . . . approved by the FDA for the prevention of migraine," "three antibodies to CGRP and its receptor in Phase 3 development for the prevention of migraine by Alder Biopharmaceuticals, Inc.[,] Teva Pharmaceutical Industries Ltd., and Eli Lilly and Company, with a fourth product developed by Amgen Inc., which is in a co-marketing partnership with Novartis International AG, approved by the FDA in May 2018," and "a number of medical devices that have been marketed for the treatment of migraine, including Cefaly and the Spring TMS device").)

place at the time of the IPO. (*See* Oral Arg. Tr. 30:22–24, ECF No. 55.) But the Amended Complaint does not appear to make either allegation. (*See* Am. Compl. ¶ 120(iii)(a) (alleging that "electroCore's agreements were limited").) And Plaintiff does not otherwise dispute that electroCore's "access negotiations" with insurance plans had "entered the active clinical review stage" at the time of the IPO. (*See id.* ¶ 120.)

Plaintiff asserts that the Registration Statement omitted information regarding payor coverage. Specifically, gammaCore was not on CVS's formulary, the "list of drugs and services covered by a[] [payor]." (*Id.* ¶¶ 70, 75.) electroCore's agreement with CVS "requir[ed] patients to have tried and had no success with three other treatments before gammaCore." (*Id.* ¶ 120(iii)(a).) And gammaCore was ineligible for the "Healthcare Common Procedure Coding System" ("HCPCS") and "may not [have been] eligible" for an "E-Code for Durable Medical Equipment"; this ostensibly made it more difficult for electroCore to reach agreements with commercial payors. (*Id.* ¶¶ 77, 120(iii)(b).)

Defendants urge the Court to apply the "bespeaks caution" doctrine to forward-looking statements, including "statements about plans to . . . secure greater payor reimbursement." (*See* Mot. to Dismiss at 27–29.) The "bespeaks caution" doctrine provides that when

> forecasts, opinions or projections are accompanied by meaningful cautionary statements, the forward-looking statements will not form the basis for a securities fraud claim if those statements did not affect the "total mix" of information the document provided investors. In other words, cautionary language, if sufficient, renders the alleged omissions or misrepresentations immaterial as a matter of law.

In re Donald J. Trump Casino Sec. Litig.—Taj Mahal Litig., 7 F.3d 357, 371 (3d Cir. 1993).

Plaintiff, however, appears to allege that statements about payor reimbursement omitted *present* facts. For example, the language in the Amended Complaint suggests that the Registration Statement did not disclose gammaCore's *present* ineligibility for the "HCPCS" and

"E-Code for Durable Medical Equipment" at the time of the IPO. (*See* Am. Compl. ¶¶ 77, 79.)[4] The "bespeaks caution" doctrine provides no protection for omissions of present facts. *See In re Westinghouse Sec. Litig.*, 90 F.3d 696, 709–10 (3d Cir. 1996); *Wilson v. Merrill Lynch & Co.*, 671 F.3d 120, 130 (2d Cir. 2011) (explaining that "[c]autionary words about future risk cannot insulate from liability the failure to disclose that the risk has transpired"). Therefore, the Registration Statement's projections of payor reimbursement are not immaterial as a matter of law under the "bespeaks caution" doctrine.

Still, Plaintiff has not demonstrated that a reasonable investor would plausibly find the projections misleading. "[A]n investor reads each statement within [a registration statement], whether of fact or of opinion, in light of all its surrounding text, including hedges, disclaimers, and apparently conflicting information." *See Omnicare*, 575 U.S. at 190. The Registration Statement provided several disclaimers about the current state of coverage. (*See, e.g.*, Registration Statement at 14 (stating that "[m]any third-party payors do not currently cover VNS for any indications other than epilepsy because they have determined all other VNS modalities to be investigational or experimental"); *id.* at 15 (disclosing that "no uniform policy of coverage and reimbursement for [gammaCore] exists among third-party payors" and, "[t]herefore, coverage and reimbursement for [gammaCore] can differ significantly from payor to payor").)[5]

[4] It is less clear whether the CVS Caremark Agreement's limitation "requiring patients to have tried and had no success with three other treatments before gammaCore" was in place at the time of the IPO. On the one hand, the limitation is based on a statement by electroCore's CEO more than ten months after the IPO, and the CEO's statement does not imply that the limitation existed before the CVS Caremark Agreement "went into effect" in January 2019. (*See* Am. Compl. ¶¶ 180–81.) On the other hand, the Amended Complaint appears to suggest that the limitation was in place as part of electroCore's agreement with CVS Caremark at the time of the IPO. (*See id.* ¶¶ 120(iii)(a), 179(iii)(a).)

[5] The Registration Statement also included cautionary language about future coverage. (*See, e.g.*, Registration Statement at 14–15, 128.)

In light of these disclaimers, Plaintiff has not plausibly alleged that the Registration Statement's coverage projections imply that electroCore's payor agreements covered gammaCore without limitations. Nor has Plaintiff plausibly alleged that the coverage projections suggest that electroCore was necessarily eligible for certain diagnostic codes. (*See* Am. Compl. ¶ 120(iii)(b) (stating that ineligibility for certain diagnostic codes made it "more difficult," but not impossible, to reach agreements with payors).)

Nor do omissions about insurance coverage support Plaintiff's § 11 claim. Plaintiff appears to imply that gammaCore was not covered by any insurer when the Registration Statement was filed. (*See id.* ¶¶ 66, 70, 89.) Plaintiff also highlights insurers' limited negotiation periods. (*See id.* ¶ 87.) But those omissions do not plausibly make the Registration Statement's disclosure about continuing "access negotiations" misleading; the fact that electroCore's access negotiations were progressing did not suggest that gammaCore was covered by insurers at the time of the IPO.

3. Physician Acceptance

Plaintiff has not plausibly alleged that the Registration Statement made false statements about physicians' acceptance of gammaCore. The Registration Statement provides some information about electroCore's arrangements with physicians, projections of "targeted" physicians, and potential physician benefits. (*See* Registration Statement at 53 (indicating that electroCore had "entered into consulting agreements and other arrangements with physicians, including some who have ownership interests in [electroCore] and/or prescribe [electroCore's] products to patients"); *id.* at 97 (projecting that, "[i]n the first year following our commercial launch into migraine, [electroCore] expect[s] to be able to target 120 national headache centers and approximately 6,400 physicians"); *id.* at 130 (noting that, in the "Proprietary gammaCore

Ecosystem," "[p]hysicians can enter prescriptions through a web-based interface engaging our trained care specialists to register new patients").) But Plaintiff has not suggested that those statements were false when made. (*See* Am. Compl. ¶ 120(iii)(c).)

Nor has Plaintiff stated a claim under § 11's omissions provision. Plaintiff alleges that the Registration Statement did not disclose physicians' "reticen[ce] to prescribe gammaCore." (*Id.*) But that omission does not plausibly make other statements, read in the context of the Registration Statement as a whole, misleading. In fact, the Registration Statement's disclaimers about barriers to physician acceptance are more forceful than any boasts on that score.[6] Therefore, Plaintiff has not plausibly asserted that the Registration Statement contained actionable omissions regarding physician acceptance.

[6] (*See, e.g.*, Registration Statement at 6 ("We must demonstrate to physicians the merits of [gammaCore] compared to those of our competitors."); *id.* at 14–15 ("If physicians or insurers do not find our clinical data compelling or wish to wait for additional studies, they may choose not to use or provide coverage and reimbursement for gammaCore."); *id.* at 16 ("In order for [gammaCore] to gain widespread adoption, we must successfully demonstrate to physicians the merits of [gammaCore] for the acute treatment of [cluster headaches] and the acute treatment of migraine, compared to our competitors' products . . . ."); *id.* ("Acceptance of [gammaCore] depends on educating physicians as to the distinctive characteristics, perceived benefits, safety, ease of use and cost-effectiveness of [gammaCore] as compared to our competitors' products, and communicating to physicians the proper use of [gammaCore]."); *id.* ("If we do not receive support from physicians or long-term data does not show the benefits of using [gammaCore], physicians may not use it."); *id.* at 25 ("We have . . . limited established relationships with physicians . . . ."); *id.* at 27 ("[W]e face a particular challenge overcoming the long-standing practices by some physicians of using the headache products of our larger, more established competitors. Physicians who use our competitors' products for the treatment of cluster and migraine headache may be reluctant to try new products from a source with which they are less familiar."); *id.* ("[P]hysicians may be slower to adopt or recommend [gammaCore]."); *id.* at 29 ("If we fail to successfully promote and maintain our brand, or if we incur substantial expenses in an unsuccessful attempt to promote and maintain our brand, [gammaCore] may not be accepted by physicians . . . ."); *id.* at 129 ("Decreases in third-party reimbursement for our products or decisions by third-party payors to not cover our products could reduce physician utilization of our products . . . .").)

4. Financial Challenges

Plaintiff has not plausibly demonstrated that the Registration Statement made false claims about electroCore's financial performance. According to Plaintiff, the Registration Statement "claimed that the voucher program would be temporary." (*Id.* ¶ 119.) The paragraph of the Registration Statement cited by Plaintiff, however, says nothing about the temporary nature of the voucher program. (*See* Registration Statement at 78.) Nor do other parts of the Registration Statement appear to discuss the temporary nature of the voucher program. Plaintiff does not seem to suggest that the Registration Statement made other false statements about electroCore's financial challenges.

Plaintiff also contends that the Securities Act Defendants omitted material information regarding financial challenges. According to Plaintiff, the Registration Statement failed to disclose that "struggl[es] with physician adoption . . . and insurance coverage" led to "increasing cash outlays in the form of product discounts, long-term use of voucher programs, . . . additional sales personnel[,] . . . unsustainable cash burn[,] and an inability to increase revenues." (Am. Compl. ¶ 3; *see also id.* ¶ 120(iv).) Additionally, Plaintiff alleges that the Securities Act Defendants failed to disclose that electroCore's voucher program contributed to financial losses. (*See id.* ¶ 120(iii)(d).)

The Registration Statement disclosed at least some aspects of electroCore's financial challenges. The Registration Statement contained information about increasing losses. (*See, e.g.*, Registration Statement at 13.) The Registration Statement cautioned that electroCore would need to obtain additional funding. (*See, e.g.*, *id.* at 6, 13.) The Registration Statement acknowledged that electroCore was offering pharmaceutical distribution discounts, vouchers, and assistance with co-payments. (*See, e.g.*, *id.* at F-33.) The Registration Statement identified electroCore's

need to hire additional sales personnel. (*See, e.g.*, *id.* at 25.) The Registration Statement clarified that electroCore's revenue "reflects only gammaCore units sold either for new patients, or existing patients[']refills, that are not related to [its] voucher program." (*Id.* at 75.) And the Registration Statement explained that "[t]he transaction price of the devices estimated to be redeemed through vouchers are recognized as contra-revenue" (*id.* at F-33), meaning a "deduction from revenue" (Mot. to Dismiss at 18). The alleged omissions submitted by Plaintiff did not plausibly make statements about electroCore's financial challenges misleading. Therefore, the alleged omissions do not support a tenable § 11 claim.

5. Product Challenges

Plaintiff asserts that the Securities Act Defendants failed to disclose the fact that gammaCore was "most often regarded as a supplemental treatment instead of a primary treatment for migraines." (Am. Compl. ¶ 120(ii).) The Registration Statement, however, at least mentioned gammaCore's potential use as a supplemental treatment; it indicated that the "PREVA" clinical trial was "designed to assess the superiority of adjunctive use of [gammaCore] with standard of care medications in comparison to standard of care medication alone." (Registration Statement at 115.) In any event, Plaintiff has not demonstrated that omitting additional information about gammaCore's use as a supplemental treatment plausibly made other statements misleading. Therefore, Plaintiff has not alleged an actionable omission under § 11.

6. Personnel Challenges

Plaintiff argues that the Registration Statement failed to disclose that electroCore's Chief Executive Officer ("CEO"), Chief Financial Officer ("CFO"), and other senior management "were poised to leave [electroCore] soon after the IPO." (Am. Compl. ¶ 120(v).) But Plaintiff does not plead any facts plausibly demonstrating that, at the time of the IPO, any executive

planned to leave. Because the omission was not "misleading at the time it was made," it is not actionable. *See Williams*, 869 F.2d at 244 (quoting *In re NAHC, Inc. Sec. Litig.*, 306 F.3d 1314, 1330 (3d Cir. 2002)). Moreover, the Registration Statement disclosed the risk that executive officers could leave electroCore. (*See* Registration Statement at 29 ("All of our executive officers and other employees are at-will employees, and therefore may terminate employment with us at any time with no advance notice.").)

C. *Item 303 of Regulation S-K*

Plaintiff asserts that the Securities Act Defendants violated Item 303 of Regulation S-K. (*See* Am. Compl. ¶ 121.) The version of Item 303 in effect when the Registration Statement was filed required, in relevant part, the disclosure of "any known trends or uncertainties that have had or that the registrant reasonably expects will have a material . . . impact on net sales or revenues or income." 17 C.F.R. § 229.303(a)(3)(ii) (2017). "Disclosure is required where the trend is both (1) known to management and (2) reasonably likely to have material effects on the registrant's financial condition or results of operations." *Stadnick v. Vivint Solar, Inc.*, 861 F.3d 31, 39 (2d Cir. 2017) (internal quotation marks omitted). Considering the extent of the Registration Statement's disclosures, Plaintiff does not identify known, material trends or uncertainties that were not disclosed at the time of electroCore's IPO.

D. *Item 105 of Regulation S-K (Previously Codified as Item 503)*

Plaintiff further argues that the Securities Act Defendants violated Item 105 of Regulation S-K. (*See* Am. Compl. ¶ 122.) Item 105 was previously codified as Item 503. *Jaroslawicz v. MT&T Bank Corp.*, 962 F.3d 701, 705 (3d Cir. 2020). The version of Item 503(c) in effect at the time of electroCore's IPO required a "discussion of the most significant factors that make the offering speculative or risky." 17 C.F.R. § 229.503(c) (2011). "The 'most

significant factors' standard is 'considerably higher' than the general [*Basic Inc. v. Levinson*, 485 U.S. 224 (1988),] materiality standard." *Howard v. Arconic Inc.*, 395 F. Supp. 3d 516, 572 (W.D. Pa. 2019) (quoting *In re BMP Billiton Ltd. Sec. Litig.*, 276 F. Supp. 3d 65, 89 (S.D.N.Y. 2017)).[7]

Plaintiff has not plausibly pled that the alleged omissions are the "most significant factors" making an investment in electroCore risky. The omitted details in this case are not as significant as omissions that have violated Item 503(c) (or Item 105's recodification of Item 503(c)) in other cases. *See, e.g.*, *Jaroslawicz*, 962 F.3d at 714 (concluding that a defendant plausibly violated Item 105 by "omitt[ing] company-specific detail about its compliance program," knowing "that the state of its compliance program would be subject to extensive review from federal regulators" and that "failure to pass regulatory scrutiny could sink [the defendant's] merger"); *Silverstrand Invs. v. AMAG Pharm., Inc.*, 707 F.3d 95, 97, 103–06 (1st Cir. 2013) (concluding that the defendant plausibly violated Item 503(c) by failing to disclose "23 reports of serious adverse effects," including a death, two life-threatening reactions, and fourteen hospitalizations, "linked to . . . a make-or-break drug for [the defendant]'s future"). "[Plaintiff's] theory would conflate Item 503(c)'s 'most significant' standard with required disclosure of *any* fact that might present any risk. But mandatory disclosures are limited." *See Howard*, 395 F. Supp. 3d at 573.

Moreover, although "[g]eneric or boilerplate discussions" of the most significant factors are insufficient, *see Silverstrand*, 707 F.3d at 103, the Registration Statement disclosed, at the level of specificity required by Item 503(c), the risks that apparently manifested. Those risks

[7] *Basic*'s materiality standard requires "a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." *Basic Inc. v. Levinson*, 485 U.S. 224, 231–32 (1988).

include company-specific risks regarding competition, payor coverage, physician acceptance, and financial challenges, among other risks. *See supra* Section II.B. "These are the kinds of company-specific facts and circumstances that Item 503(c) and caselaw contemplate." *See Howard*, 395 F. Supp. 3d at 573–74.

For the foregoing reasons, Plaintiff has not stated a plausible claim under § 11 of the Securities Act.

III. Count 2: Section 12(a)(2) of the Securities Act

To establish a violation of § 12(a)(2) of the Securities Act, a plaintiff must demonstrate, among other things, that a prospectus or oral communication "includes an untrue statement of a material fact or omits to state a material fact necessary in order to make the statements, in the light of the circumstances under which they were made, not misleading." 15 U.S.C. § 77*l*(a)(2). Because Plaintiff's § 12(a)(2) claims are also based on alleged misstatements and omissions in the Registration Statement, Plaintiff has not plausibly pled this element. *See supra* Section II. Therefore, the Court dismisses Count 2.

IV. Count 3: Section 15 of the Securities Act

Section 15 of the Securities Act is a "form of derivative liability." *In re Adams Golf, Inc. Sec. Litig.*, 381 F.3d 267, 273 n.3 (3d Cir. 2004). It provides, in pertinent part, that any defendant who "controls any person liable under [§ 11 or § 12] shall also be liable jointly and severally with and to the same extent as such controlled person to any person to whom such controlled person is liable." 15 U.S.C. § 77o. "[T]he plaintiff must prove that one person controlled another person or entity and that the controlled person or entity committed a primary violation of the securities laws." *Suprema*, 438 F.3d at 284. Plaintiff has not demonstrated that a controlled person or entity violated §§ 11 or 12(a)(2) of the Securities Act. *See supra* Sections II, III.

Therefore, Plaintiff's § 15 claim is unavailing.

V. Timeliness of Securities Act Claims

A. *Timeliness of Claims Against All Defendants*

Under the Securities Act, "[n]o action shall be maintained to enforce any liability created under [§§ 11 or 12(a)(2)] unless brought within one year after the discovery of the untrue statement or the omission, or after such discovery should have been made by the exercise of reasonable diligence." 15 U.S.C. § 77m.

Defendants argue that Plaintiff's Securities Act claims are untimely because publicly available press releases and news articles revealed pre-IPO developments regarding electroCore's competitors. (*See* Mot. to Dismiss at 29–32.) According to Defendants, "[a] reasonably diligent plaintiff would have discovered [the developments] immediately after the IPO," but "this case was not filed until . . . over a year later." (*Id.* at 31–32.)

Although the Securities Act claims are dismissed for other reasons, they are not time-barred. "[A] fact is not deemed 'discovered' until a reasonably diligent plaintiff would have sufficient information about that fact to adequately plead it in a complaint . . . with sufficient detail and particularity to survive a [Rule] 12(b)(6) motion to dismiss." *Pension Tr. Fund for Operating Eng'rs v. Mortg. Asset Securitization Transactions, Inc.*, 730 F.3d 263, 275 (3d Cir. 2013). Omitting the specific developments in the press releases and news articles does not make the Registration Statement misleading: The statements about electroCore's competitive strengths are opinions, and the Registration Statement's competition-related disclosures are extensive and specific to electroCore. *See supra* Section II.B.1. The Court concludes that the Amended Complaint would not have overcome a Rule 12(b)(6) motion to dismiss even if it had pled the

information in the press releases and news articles. Therefore, the Securities Act claims are not time-barred.

B. *Timeliness of Claims Against Defendants Ondra, CV II, and CV IV*

Defendants separately argue that all claims against Defendants Ondra, CV II, and CV IV are untimely. (*See* Mot. to Dismiss at 40.) Plaintiff added those claims when she filed the Amended Complaint on July 17, 2020. (ECF No. 31.) Defendants assert that the claims were added "well over a year after Plaintiffs allege the truth was revealed." (Mot. to Dismiss at 40 (citing Am. Compl. ¶¶ 180–88)).[8]

The timeliness of the Securities Act claims against Ondra, CV II, and CV IV seems to depend on whether those claims "relate back" to the original Complaint, an issue the parties did not brief. Rule 15 of the Federal Rules of Civil Procedure provides, in relevant part, that an amendment of a pleading relates back to the date of the original pleading when

> (C) the amendment changes the party . . . against whom a claim is asserted, if Rule 15(c)(1)(B) is satisfied and if, within the period provided by Rule 4(m) for serving the summons and complaint, the party to be brought in by amendment:
>
> (i) received such notice of the action that it will not be prejudiced in defending on the merits; and
>
> (ii) knew or should have known that the action would have been brought against it, but for a mistake concerning the proper party's identity.

Fed. R. Civ. P. 15(c)(1).

A statute-of-limitations defense can be raised in a Rule 12(b)(6) motion to dismiss "only if the time alleged in the [complaint] shows that the cause of action has not been brought within the statute of limitations." *Schmidt v. Skolas*, 770 F.3d 241, 249 (3d Cir. 2014) (internal

[8] Plaintiffs allege that the "truth was revealed" beginning in May 2019. (*See* Am. Compl. ¶ 180.)

quotation marks omitted). "Since the applicability of the statute of limitations usually involves questions of fact for the jury, if the bar is not apparent on the face of the complaint, then it may not afford the basis for a dismissal of the complaint under Rule 12(b)(6)." *Fried v. JP Morgan Chase & Co.*, 850 F.3d 590, 604 (3d Cir. 2017) (citations omitted).

The Court's "relation-back" analysis requires consideration of facts outside the Amended Complaint. Consider the issue of notice. Courts can impute notice under Rule 15(c)(1)(C) through the "shared attorney" method or the "imputed interest" method. *See Garvin v. City of Philadelphia*, 354 F.3d 215, 222–27 (3d Cir. 2003). Under the "shared attorney" method, the relevant inquiry is whether notice can be imputed to the added defendant "by virtue of representation [he] shared with a defendant originally named in the lawsuit." *Id.* at 223. Under the "identity of interest" method, the relevant inquiry is whether "the parties are so closely related in their business operations or other activities that filing suit against one serves to provide notice to the other of the pending litigation." *Id.* at 227. Under either method, the Court would need to consider facts outside of the Amended Complaint. Likewise, the Court would need to consider external facts in evaluating issues of prejudice and knowledge under Rule 15(c)(1)(C). Accordingly, it is premature at this juncture to consider Defendants' statute-of-limitations argument as to Defendants Ondra, CV II, and CV IV. *See McCall v. City of Philadelphia*, 2020 WL 4584173, at *4 (E.D. Pa. Aug. 10, 2020) (declining to consider a statute-of-limitations defense where assessing the plaintiff's relation-back argument would "require[] examination of evidence extraneous to the Amended Complaint").[9]

[9] Based on the allegations in the Amended Complaint, Plaintiff's Exchange Act claims against Defendants Ondra, CV II, and CV IV are timely. The statute of limitations for § 10(b) claims runs "2 years after the discovery of the facts constituting the violation" or "5 years after such

VI. Count 4: Section 10(b) of the Exchange Act and SEC Rule 10b-5

Section 10(b) of the Exchange Act prohibits the "use or employ[ment], in connection with the purchase or sale of any security[,] . . . [of] any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe." 15 U.S.C. § 78j(b). Pursuant to its authority under § 10(b) of the Exchange Act, the SEC promulgated Rule 10b-5, making it unlawful for any person:

> (a) To employ any device, scheme, or artifice to defraud,
>
> (b) To make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading, or
>
> (c) To engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person,
>
> in connection with the purchase or sale of any security.

17 C.F.R. § 240.10b-5. "To adequately allege a § 10(b) securities fraud claim, a plaintiff must plead (1) a material misrepresentation or omission, (2) scienter, (3) a connection between the misrepresentation or omission and the purchase or sale of a security, (4) reliance upon the misrepresentation or omission, (5) economic loss, and (6) loss causation." *In re Hertz Glob. Holdings Inc.*, 905 F.3d 106, 114 (3d Cir. 2018) (internal quotation marks omitted).

A. *Alleged Misstatements and Omissions*

Plaintiff incorporates her allegations regarding the Registration Statement into her Exchange Act claims. (*See* Am. Compl. ¶ 159.) Because those allegations fail under Rule 8's pleading requirements, *see supra* Section II.B., they also fail under Rule 9(b)'s pleading

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violation." *See Merck & Co., Inc. v. Reynolds*, 559 U.S. 633, 638 (2010) (quoting 28 U.S.C. § 1658(b)). Plaintiff added Defendants Ondra, CV II, and CV IV less than two years after she alleges to have discovered the facts underlying her Exchange Act claims.

requirements. Plaintiff, however, also avers that Defendants' post-IPO public statements and filings contained additional material misrepresentations and omissions. (*See* Am. Compl. ¶¶ 160-–79.)

1. August 2018 Press Release and Q2 2018 10-Q

electroCore's August 13, 2018 press release announced the company's second-quarter financial results. (*Id.* ¶ 160.) In the press release, electroCore's CEO, Defendant Amato, stated, "I am encouraged by our second quarter financial results. . . . I believe our successful IPO will not only enable us to expand our commercial presence, but also allows us to build upon our growing list of positive clinical studies." (*Id.*) electroCore's Q2 2018 10-Q reiterated the second-quarter financial results. (*Id.* ¶ 161.)

Plaintiff asserts that the statements in those documents were misleading because they failed to disclose "(i) that gammaCore did not enjoy any advantages over other acute treatments for migraines and episodic cluster headaches; (ii) that gammaCore's voucher program was not effective in increasing adoption of gammaCore and in fact was negatively [a]ffecting reimbursement by payors . . . and increasing Company costs; and (iii) that the Company's business plan and strategy was unsustainable because electroCore lacked sufficient revenue to be profitable." (*Id.* ¶ 162.)

Plaintiff has not pled with particularity that the statements in the August 2018 press release and Q2 2018 10-Q plausibly implied that gammaCore had advantages over other treatments, that electroCore's voucher program was effective in increasing adoption of gammaCore or payor reimbursement, or that gammaCore's business plan and strategy were sustainable. Therefore, the alleged omissions in those documents do not support Plaintiff's claims under § 10(b) of the Exchange Act and SEC Rule 10b-5.

2. November 2018 Press Release, Q3 2018 10-Q, and Earnings Call

On November 13, 2018, electroCore issued a press release announcing third-quarter financial results. (*Id.* ¶ 163.) The press release referenced "[c]ommercial payer coverage for 35 million lives beginning in the first quarter of 2019." (*Id.*) Defendant Amato stated, "With continuing discussions and negotiations for payer coverage for an additional 90 million lives, and our increasing base of prescribing physicians, we are well positioned for gammaCore to be an early option for patients suffering from migraine and episodic cluster headaches." (*Id.*) The press release also explained, "The decrease in net sales . . . contrasts with the significant increase in prescriptions during the same period as a result of a vast majority of prescriptions being dispensed under our patient voucher and copay assistance programs. . . . [electroCore] expects this trend to be temporary . . . ." (*Id.*) The Q3 2018 10-Q affirmed the financial results disclosed in the press release. (*Id.* ¶ 166.)

On a November 13, 2018 earnings call, Defendant Amato explained,

> Currently we have multiple reimbursement agreements in place[,] [t]he first of which is the CVS Caremark agreement, which will go into effect January 1, 2019. Under this agreement, we have been advised that approximately 30 million of the 65 million U.S. individuals managed by CVS Caremark will have access to our therapy as a Tier 3 product beginning in January of 2019. Potential access to the remaining 35 million lives will be gained through continuing negotiations with the payers within the CVS network.

(*Id.* ¶ 164.) Defendant Vraniak, electroCore's CFO, noted that electroCore's decrease in revenue was "primarily due to the contra-revenue remaining as a result of [electroCore's] voucher program." (*Id.* ¶ 165.)

Plaintiff argues that those statements were misleading largely for the same reasons as the August 2018 press release and Q2 2018 10-Q. (*See id.* ¶ 167.) Plaintiff adds that electroCore's payor agreements "had restrictions limiting the patient population the payors would cover" and

"there were numerous issues with payor formularies and diagnostic codes impeding payor reimbursement agreements." (*Id.*)

Plaintiff has not adequately demonstrated that the statements were misleading. Plaintiff has not plausibly alleged that the general statement about gammaCore's potential as an "early option" implied that gammaCore had certain advantages over its competitors. Plaintiff has not plausibly alleged that references to continuing negotiations with payors suggested that electroCore's payor agreements fully covered gammaCore, that gammaCore was included on formularies, or that gammaCore was eligible for certain diagnostic codes. (*See id.* ¶¶ 163–64.) Plaintiff has not plausibly alleged that Defendant Vraniak's statement that the proceeds from the voucher program had been recognized as "contra-revenue" indicated that the voucher program was "effective in increasing adoption of gammaCore," increasing payor reimbursement, or decreasing costs. (*See id.* ¶ 165.) And Plaintiff has not plausibly alleged that electroCore's expectation regarding net sales implied that electroCore's business plan and strategy were sustainable. (*See id.* ¶ 163.)

3. March 2019 Press Release and Earnings Call

On March 27, 2019, electroCore issued a press release announcing fourth-quarter financial results. (*Id.* ¶ 168.) The fourth-quarter results reflected an increase in reported net sales from the fourth quarter of 2017 and the third quarter of 2018. (*Id.*) The results also reflected an increase in operating loss from the fourth quarter of 2017 and the third quarter of 2018. (*Id.*) Defendant Amato stated, "Notably, our fourth quarter results do not reflect the addition of covered lives from CVS Caremark, Highmark and the recently announced Federal Supply Schedule contract, all of which commenced reimbursement of gammaCore[] beginning in the first quarter 2019." (*Id.*)

electroCore held an earnings conference call on the same day. (*Id.* ¶ 169.) Defendant Amato stated, among other things, that fourth-quarter financial results did not yet "reflect the positive effect reimbursement will have for gammaCore, which largely started in this year"; electroCore "remain[s] on track to achieve 75 million covered lives by the middle of this year and 100 million by the end of the year"; impending payor reimbursement would "offset to a great degree some of th[e] burden" of cash burn; and electroCore "dispensed approximately $1.7 million worth of gammaCore prescriptions pursuant to ongoing promotional programs . . . designed for patients who do not yet have reimbursement, otherwise known as demand revenue." (*Id.* ¶¶ 169, 171.) Defendant Vraniak expressed electroCore's "continue[d] . . . belie[f] that [the company's promotional programs] are accomplishing our objectives of providing patient therapy at no charge, demonstrating the benefits of gammaCore therapy to physicians who write prescriptions[,] and promoting U.S. commercial payer coverage and coverage discussions as a result of patient and physician demand." (*Id.* ¶ 170.)

Plaintiff asserts that these statements were misleading for the same reasons as the November 2018 press release, earnings call, and Q3 2018 10-Q. (*See id.* ¶ 172.) But Plaintiff has not plausibly alleged that the positive projection about payor coverage implies that electroCore's payor agreements fully covered gammaCore, that gammaCore was included on formularies, or that gammaCore was eligible for certain diagnostic codes. Plaintiff has not plausibly alleged that Defendant Amato's statement about electroCore's promotional programs suggests that the voucher program was effective in increasing adoption of gammaCore, increasing payor reimbursement, or decreasing costs. Relatedly, Plaintiff has not plausibly alleged that electroCore's opinion about its promotional programs was not honestly held at the time, that untrue facts were embedded in the opinion, or that particular facts "going to the basis for" the

opinion made it misleading. *See Omnicare*, 575 U.S. at 184–86, 194. Nor has Plaintiff plausibly alleged that disclosures of temporary increases in revenue or payor reimbursement—particularly when presented alongside disclosures of increased operating loss—indicated that electroCore's business model or strategy were sustainable. Therefore, Plaintiff has not stated an Exchange Act claim based on the March 2019 press release and earnings call.

4. 2018 Form 10-K

On March 28, 2019, electroCore filed its 2018 Form 10-K. (Am. Compl. ¶ 173.) The 10-K disclosed, among other things, purported competitive strengths, current acute migraine treatments and their limitations, current therapies for migraine prevention and their limitations, electroCore's plans to seek label expansion with the FDA, and electroCore's strategy. (*See id.* ¶¶ 174–78.)

Plaintiff argues that the 2018 Form 10-K was misleading for several reasons. Plaintiff avers that the 10-K did not disclose that "gammaCore did not enjoy any competitive advantages over other treatments for [cluster headaches] and migraines." (*Id.* ¶ 179(i).) Like the competitive strengths listed in the Registration Statement, however, the competitive strengths listed in the 2018 Form 10-K are opinions. (*See id.* ¶ 174.) And for the same reasons that competition-related opinions in the Registration Statement are nonactionable, competition-related opinions in the 2018 Form 10-K are nonactionable. *See supra* Section II.B.1.

Additionally, Plaintiff asserts that the 2018 Form 10-K did not disclose that gammaCore was "most often regarded as a supplemental treatment instead of a primary treatment for migraine." (Am. Compl. ¶ 179(ii).) The 10-K, however, discussed the FDA's 510(k) clearance "for an expanded label for [gammaCore] for adjunctive use for the preventive treatment of cluster headache in adult patients." (2018 Form 10-K at 51, 53, 55, F-8, Defs.' Ex. 2, ECF No.

42-4.) Like the Registration Statement, the 10-K indicated that the PREVA clinical trial was "designed to assess the superiority of adjunctive use of [gammaCore] with standard of care medications in comparison to standard of care medication alone." (*Id.* at 22.) And Plaintiff has not demonstrated that omitting other information about gammaCore's use as a supplemental treatment plausibly made other statements in the 10-K misleading.

Plaintiff also avers that the 2018 Form 10-K did not disclose that electroCore's payor agreements were limited and that gammaCore was ineligible for certain diagnostic codes. (Am. Compl. ¶¶ 179(iii)(a)–(b).) These arguments do not support Plaintiff's Exchange Act claims for the same reasons they do not support Plaintiff's Securities Act claims. The 10-K disclosed current challenges in obtaining third-party payor reimbursement. (*See* 2018 Form 10-K at 49 (disclosing that "[m]any third-party payers do not currently cover VNS for any indications other than epilepsy because they have determined all other VNS modalities to be investigational or experimental"); *id.* (stating that, "in the United States, no uniform policy of coverage and reimbursement for [gammaCore] exists among third-party payers" and, "[t]herefore, coverage and reimbursement for [gammaCore] can differ significantly from payer to payer").) Plaintiff has not adequately alleged that omitting the limitations of electroCore's CVS Caremark Agreement and gammaCore's ineligibility for diagnostic codes made the 10-K's statements about payor reimbursement misleading.

Moreover, Plaintiff submits that the 10-K failed to disclose physicians' "reticen[ce] to prescribe gammaCore." (Am. Compl. ¶ 179(iii)(c).) But the 10-K discussed challenges regarding

physician acceptance.[10] Plaintiff has not plausibly demonstrated that omitting additional barriers to physician acceptance made other statements in the 10-K misleading.

Plaintiff also alleges that the 2018 Form 10-K did not disclose electroCore's "dependen[ce] on its voucher program," which was allegedly increasing losses, failing to increase revenues, and "substantially impeding" electroCore's progress with payors. (*Id.* ¶ 179(iii)(d).) The 10-K, however, indicated that electroCore's "net sales reflect only gammaCore and gammaCore Sapphire units sold either for new patients, or existing patients' refills, and none of the . . . units prescribed and dispensed through our voucher program." (2018 Form 10-K at 97.) No other statement in the 10-K appears to imply that the voucher program was promoting progress with payors.

Relatedly, Plaintiff submits that the 2018 Form 10-K failed to disclose that "all of the above" would "require significant cash outlays, accelerating cash burn and making the purported business strategies unsustainable." (Am. Compl. ¶ 179(iv).) Like the Registration Statement,

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[10] (*See, e.g.*, 2018 Form 10-K at 47, Defs.' Ex. 2, ECF No. 42-4 ("We face a variety of challenges and risks that we will need to address and manage as we pursue our strategy, including our ability to . . . achieve market acceptance . . . among physicians . . . ."); *id.* at 49 ("If physicians . . . do not find our clinical data compelling or wish to wait for additional studies, they may choose not to use or provide coverage and reimbursement for gammaCore."); *id.* at 51 ("We must demonstrate to physicians the merits of [gammaCore] compared to those of our competitors."); *id.* ("If we do not receive support from physicians or long-term data does not show the benefits of using [gammaCore], physicians may not use it."); *id.* at 59 ("We have . . . limited established relationships with physicians . . . ."); *id.* at 60 ("Many of the companies developing or marketing competing products enjoy several advantages over us, including . . . long established relationships with physicians and hospitals . . . ."); *id.* at 61 ("[W]e face a particular challenge overcoming the long-standing practices by some physicians of using the headache products of our larger, more established competitors. Physicians who use our competitors' products for the treatment of cluster and migraine headache may be reluctant to try new products from a source with which they are less familiar."); *id.* at 63 ("If we fail to successfully promote and maintain our brand, or if we incur substantial expenses in an unsuccessful attempt to promote and maintain our brand, [gammaCore] may not be accepted by physicians . . . .").)

however, the 2018 Form 10-K disclosed electroCore's use of discounts, co-payment assistance, and vouchers, (*see, e.g.*, 2018 Form 10-K at 31, 96–97, F-14), as well as the need to hire additional personnel, (*see, e.g.*, *id.* at 59). The 10-K also warned, "Because of the numerous risks and uncertainties associated with our commercialization efforts, as well as research and clinical development activities, we are unable to predict the timing or amount of increased expenses, or when, if ever, we will be able to achieve or maintain profitability." (*Id.* at 47.) Plaintiff has not plausibly demonstrated that omitting additional facts about financial challenges made the 10-K misleading.

Plaintiff also asserts that the 2018 Form 10-K misrepresented the sufficiency of data regarding gammaCore's potential to prevent migraines. (*See* Am. Compl. ¶¶ 92, 179(v).) But Plaintiff does not adequately explain how the 10-K's disclosures about data were misleading. The 10-K explained the results of the PREMIUM I clinical trial, which was meant to evaluate gammaCore's effectiveness in preventing migraines. (*See* 2018 Form 10-K at 14–15.) The 10-K reported that the PREMIUM I trial did not meet its primary endpoint for certain patients and that at least some of the trial's results were not statistically significant. (*Id.* at 14.) And when the 10-K was filed, the PREMIUM II trial, another migraine-prevention trial, had not yet been completed: electroCore anticipated that the trial would "complete enrollment in the first quarter of 2020 with data readout anticipated in the third quarter of 2020." (*Id.* at 15.) Plaintiff has not adequately pled that these disclosures or other parts of the 10-K misrepresented the sufficiency of electroCore's data.

Finally, Plaintiff argues that "electroCore knew by August 2019 (if not earlier) that the FDA had concerns about the robustness of electroCore's data," but that the Exchange Act Defendants "did not reveal such knowledge until forced to do so." (Am. Compl. ¶ 192.) In

September 2019, "[electroCore] revealed that the FDA had requested more information and analysis of clinical data for electroCore's 510(k) submission." (*Id.*) But Plaintiff has not pled with sufficient particularity that the Exchange Act Defendants plausibly knew about the FDA's purported concerns when the 2018 Form 10-K was filed in March 2019.

In sum, Plaintiff has not adequately pled that the Exchange Act Defendants made material misstatements or omissions in violation of § 10(b) and SEC Rule 10b-5.

B. *Scienter*

Even if Plaintiff had adequately pled material misstatements or omissions, the claims against at least some of the Exchange Act Defendants would be dismissed for lack of scienter.

Scienter is "a mental state embracing intent to deceive, manipulate, or defraud," *Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 319 (2007), and "requires a knowing or reckless state of mind," *Avaya*, 564 F.3d at 252. Under the PSLRA, the plaintiff must "state with particularity facts giving rise to a strong inference" of scienter. 15 U.S.C. § 78u-4(b)(2). A complaint adequately pleads a strong inference of scienter "only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Tellabs*, 551 U.S. at 324. "[A] plaintiff does not need to come forward with 'smoking-gun' evidence to meet the PSLRA's pleading requirements." *Hertz*, 905 F.3d at 114 (quoting *Tellabs*, 551 U.S. at 324). "Rather, . . . courts must analyze the complaint holistically to determine whether its allegations, 'taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard.'" *Id.* (quoting *Tellabs*, 551 U.S. at 323).

Plaintiff has not pled facts supporting a strong inference of scienter for at least some of the Exchange Act Defendants. "[A] § 10(b) claim cannot survive a motion to dismiss unless it is

supported by factual allegations sufficiently demonstrating each defendant's role in the alleged fraud and his or her state of mind in committing such a violation." *In re Merck & Co., Inc. Sec., Derivative, & ERISA Litig.*, 2011 WL 3444199, at *19 (D.N.J. Aug. 8, 2011) (citing *Winer Fam. Tr. v. Queen*, 503 F.3d 319, 337 (3d Cir. 2007)). The Amended Complaint contains no allegations of recklessness or knowledge of Defendants T. Errico, Cox, Atieh, Colucci, Moody, Ondra, or Tullis. And the allegation that Defendants Vraniak, Posner, and J.P. Errico were part of a "highly experienced management team," without more, is insufficient to infer scienter. *See Rahman v. Kid Brands, Inc.*, 736 F.3d 237, 247 (3d Cir. 2013) (explaining that "corporate management's general awareness of the day-to-day workings of the company's business does not establish scienter—at least absent some additional allegations of specific information conveyed to management and related to fraud" (quoting *Metzler Inv. GMBH v. Corinthian Colls., Inc.*, 540 F.3d 1049, 1068 (9th Cir. 2008)).[11] Nor does the Amended Complaint adequately plead that the Exchange Act Defendants had a "motive and opportunity" to violate § 10(b). *See Avaya*, 564 F.3d at 278 (explaining that "[m]otives that are generally possessed by most corporate directors and officers do not suffice; instead, plaintiffs must assert a concrete and personal benefit to the individual defendants resulting from this fraud"). In any event, "'motive and opportunity' may no longer serve as an independent route to scienter." *Id.* at 277. Therefore, Plaintiff has not pled facts supporting a strong inference of scienter for at least some of the Exchange Act Defendants.

[11] Because the Court concludes that Plaintiff has not adequately pled material misstatements or omissions, the Court will not consider her allegations of insider sales against Defendant J. Errico at this time. (*See* Am. Compl. ¶¶ 206–07.)

VII. Count 5: Section 20(a) of the Exchange Act

"Section 20(a) of the Exchange Act provides for liability for 'controlling person[s].'" *In re Merck & Co., Inc. Sec. Litig.*, 432 F.3d 261, 275 (3d Cir. 2005) (quoting 15 U.S.C. § 78t). "Section 20(a) makes controlling persons jointly and severally liable with the controlled person." *Id.* To establish control-person liability, "plaintiffs must prove not only that one person controlled another person, but also that the 'controlled person' is liable under the [Exchange] Act." *Belmont v. MB Inv. Partners, Inc.*, 708 F.3d 470, 484 (3d Cir. 2013). Because Plaintiff has not adequately alleged an underlying securities violation, her § 20(a) claim fails.

VIII. Leave to Amend

Plaintiff requests leave to amend the Amended Complaint upon dismissal. (Opp'n at 40 n.34.) Rule 15(a)(2) of the Federal Rules of Civil Procedure allows amendment of the pleadings with the court's leave, which should be given freely "when justice so requires." Fed. R. Civ. P. 15(a)(2). Plaintiff is granted leave to file an amended complaint within thirty (30) days, if she wishes to do so, to cure the deficiencies in the Amended Complaint identified in this Opinion.

CONCLUSION

For the foregoing reasons, Plaintiff's Motion to Strike (ECF No. 48) is granted in part and denied in part, and Defendants' Motion to Dismiss (ECF No. 42) is granted. An appropriate Order will follow.

Date: August 13, 2021

/s/ Anne E. Thompson
ANNE E. THOMPSON, U.S.D.J.